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Applicant(s): Elisabettini et al.

TECH CENTER 1600/2900

Appl. No.:

10/044,234

Filed:

January 11, 2002

Title:

BICARBONATE-BASED SOLUTIONS FOR DIALYSIS THERAPIES

Art Unit:

1616

Examiner:

Unknown

Docket No.:

DI-5782

Assistant Commissioner for Patents

Washington, DC 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 37 C.F.R. 1.97, and 37 C.F.R. 1.98, Applicants request that a citation and examination of the references cited below, and on the attached PTO-1449 form, copies of which are enclosed, be made during the course of examination of the above-identified application for United States patent.

FOREIGN PATENT DOCUMENTS

| Document No. | Date 12.01 | Country |
|-------------------|------------|---------|
| JP 56164113 - | 12-17-81 | Japan |
| EP 0 083 360 - | 07-13-83 | Europe |
| EP 0 165 933 B1- | 01-02-86 | Europe |
| WO 86/03407 - | 06-19-86 | PCT |
| EP 0 209 607_ | 01-28-87 | Europe |
| WO 87/03809 - | 07-02-87 | PCT |
| EP 0 249 667 B1 ~ | 12-23-87 | Europe |
| EP 0 277 868 A2 - | 08-10-88 | Europe |
| EP 0 278 100 A2 - | 08-17-88 | Europe |
| EP 0 399 549 A1 - | 11-28-90 | Europe |
| 0 399 918 A2 - | 11-28-90 | Europe |
| JP 2304026 - | 12-17-90 | Japan |
| 0 417 478 A1 — | 03-20-91 | Europe |
| 0 437 274 A1 — | 07-17-91 | Europe |
| EP 0 439 061 B1 ~ | 07-31-91 | Europe |
| JP 3195561 - | 08-27-91 | Japan |

| <u>Document No.</u> WO 91/18610 ~ | <u>Date</u> 12-12-91 | Country PCT |
|--------------------------------------|-------------------------|----------------|
| 0 481 257 A1 ~ | 04-22-92 | Europe |
| JP 5105633 - | 04-27-93 | Japan |
| JP 6105905 - | 04-19-94 | Japan |
| EP 0 613 688 A1 - | 09-07-94 | Europe |
| EP 0 647 145 B1 ~ | 04-12-95 | Europe |
| WO 95/19778 _ | 07-27-95 | PCT |
| JP 7252137 ~ | 10-03-95 | Japan |
| WO 96/01118 _ | 01-18-96 | PCT |
| JP 8131542 ~ | 05-28-93 | Japan |
| JP 8164199 ~ | 06-25-96 | Japan |
| WO 97/05851 ~ | 02-20-97 | PCT |
| JP 9087182 - | 03-31-97 | Japan |
| JP 9110703 ~ | 04-28-97 | Japan |
| EP 0 776 649 A2- | 06-04-97 | Europe |
| JP 9301875 — | 11-25-97 | Japan |
| FR 2 753 099 ~ | 03-13-98 | France |
| WO 98/10733 - | 03-19-98 | PCT |
| JP 10201821 - | 08-04-98 | Japan |
| JP 11004872 - | 01-12-99 | Japan |
| WO 99/01144 - | 01-14-99 | PCT |
| JP 11-9659 — | 01-19-99 | Japan |
| JP 11-19178 | 01-26-99 | Japan |
| WO 99/09953 — | 03-04-99 | PCT |
| DE 19748290 - | 05-06-99 | Germany |
| EP 0 935 967 A2 - | 08-18-99 | Europe |
| EP 1166787 — | 01-02-02 | Europe |

OTHER DOCUMENTS

- Manahan et al., Peritoneal Dialysis using bicarbonate-containing solution sterilized by ultrafiltration, The International Journal of Artificial Organs, Vol. 14 no. 8, 1999, pp. 463-465.
- _ Murphy et al., Use of an Artificial Kidney, Vol. 40, 1952, pp. 436-444.
- Tjiang, Boen San, A Clinical Study of Factors Governing its Effectiveness, Peritoneal Dialysis, p. 76, Van Gorcum & Co., Assen, The Neterlands (1959).
- Feriani et al., Short-Term Clinical Study with Bicarbonate-Containing Peritoneal Dialysis Solution, Peritoneal Dialysis International, Vol. 13, pp. 296-301 (1993).
 - . The Merck Index, 12th Ed., Merck Research Laboratories, Whitehouse Station, NJ, 9 1472 (1996).
- Odel et al., Peritoneal Lavage as an Effective Means of Extraenal Excretion. A Clinical Appraisal, American Journal of Medicine, Vol. 9, 63-88 (1950).
- Schambye et al., The Cytotoxicity of Continuous Ambulatory Peritoneal Dialysis Solutions with Different Bicarbonate/Lactate Ratios, Peritoneal Dialysis International Vol. 13, Suppl. 2, Oct. 1-4, pp. S116-S118 (1994).
- Schambye et al., Bicarbonate-versus Lactate-Based CAPD fluids: A Biocompatibility Study in Rabbits, Peritoneal Dialysis International, Vol. 12, pp. 281-286 (1992).
- Simonsen et al., Less Infusion Pain and Elevated Level of Cancer Antigen 125 by the Use of a New and More Biocompatible PD Fluid, Advances in Peritoneal Dialysis, Vol. 12, pp. 156-160 (1996).
- Ing., et al., Bicarbonate-Buffered Peritoneal Dialysis, The International Journal of Artificial Organ, Vol. 8, No. 3, p. 121-124 (1985).
- Zhou et al., Effects of an Acidic, Lactate-Based Peritoneal Dialysis Solution and its Euhydric, Bicarbonate-Based Counterpart on Neutrophilic Interacellular pH, Int. J. Artif. Organs, Vol. 16, No. 12, pp. 816-819 (1993).
- American Society for Artificial Internal Organs, 1994 Abstracts, pp 110.
- Faller et al., Loss of Ultrafiltration in Continuous Ambulatory Peritoneal Dialysis: A Role for Acetate, Peritoneal Dialysis Bulletin, January-March 1984, pp 10-13.
- Ing et al., Lactate-Containing Peritoneal Dialysis Solutions, International J. of Artificial Organs, Vol. 16, No. 10, 1993, pp 688-693.
- Ing et al., Lactate-Containing Versus Bicarbonate-Containing Peritoneal Dialysis Solutions, Peritoneal Dialysis International, Vol. 12, pp 276-277.

- Ing et al., Preparation of Bicarbonate-Containing Dialysate for Peritoneal Dialysis, International J. of Artificial Organs, Vol. 6, No. 4, 1983, pp 217-218.
- Manahan et al., Effects of Bicarbonate-Containing Versus Lactate-Containing Peritoneal Dialysis Solutions on Superoxide Production by Human Neutrophils, Artificial Organs, Vol. 13, No. 6, 1989, pp. 495-497.
- Richardson et al., Bicarbonate, L-Lactate, and D-Lactate Balance in Intermittent Peritoneal Dialysis, Peritoneal Dialysis Bulletin, Vol. 6, No. 4, 1986, pp. 178-185.
- Yatzidis, Hippocrates, A New Stable Bicarbonate Dialysis Solution for Peritoneal Dialysis: Preliminary Report, Peritoneal Dialysis International, Vol. 11, pp. 224-227.

An early and favorable consideration of this matter is respectfully requested.

Respectfully submitted,

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| TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT SP 2 3 2002 (Under 37 CFR 1.97(b) or 1.97(c)) | | | Docket No. DI-5782 | |
| 2 8 | Clisabettini et al. | | | |
| Serial No. | Filing Date | Examiner | Group Art Unit | |
| 10/044,234 | 10/044,234 January 11, 2002 Unknown | | 1616 | |
| Title: BICARBONATE-BASED SOLUTIONS FOR DIALYSIS THERAPIES Address to: Assistant Commissioner for Patents Washington, D.C. 20231 | | | | |
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| | 37 C | FR 1.97(b) | 9 | |
| 1. A The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114. | | | | |
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| CFR 1.97(b), pro Final Action und | ovided that the Information Disc | herewith is being filed after the pelosure Statement is filed before the Allowance under 37 CFR 1.311 and is accompanied by one of: | ne mailing date of a | |
| ☐ the statem | ent specified in 37 CFR 1.97(e); | | | |
| | OR | | | |
| ☐ the fee se | t forth in 37 CFR 1.17(p). | | | |
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| BICARBONATE-BASED SOLUTIONS FOR DIALYSIS THERAPIES Payment of Fee (Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p)) A check in the amount of is attached. The Assistant Commissioner is hereby authorized to charge and credit Deposit Account No. as described below. A duplicate copy of this sheet is enclosed. Charge the amount of Credit any overpayment. Charge any additional fee required. Certificate of Transmission by Facsimile* Certificate of Mailing by First Class Mail I certify that this document and authorization to charge deposited account is being facsimile transmitted to the United States Patent and Trademark Office (F (Date) | | | | | |
| Typed or Printed N | dame of Person Signing Certificate | Robert J. Buccieri Typed or Printed Name of Person | 1 Mailing Certificate | | |
| Robert M. Barrett Reg. No. 30,142 BELL, BOYD & LLOYD P.O. Box 1135 Chicago, IL 60690-1135 | y only be used if paying by ignature | Dated: September 18, 2002 | | | |
| Ph ne: 312/807-4204 | | | | | |

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| SEP 2 3 2002 | TRANSMITTAL LETTER (General - Patent Pending) | | | Docket No. DI-5782 |
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| Robert M. Barrett | | | | |
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| BELL, BOYD & LLOYD : P.O. Box 1135 | LLC | | I cértify that this docu | ment and fee is being deposited |
| Chicago, IL 60690-1135 | | | on09-18-2002 first class mail under/37 | with the U.S. Postal Service as C.F.R. 1.8 and is addressed to the |
| Phone: 312-807-4204 | | | Assistant Commissione | for Patents, Washington, D.C. |
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| | | | Signature of Pers | son Mailing Correspondence |
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| cc: | | | | of Person Mailing Correspondence |